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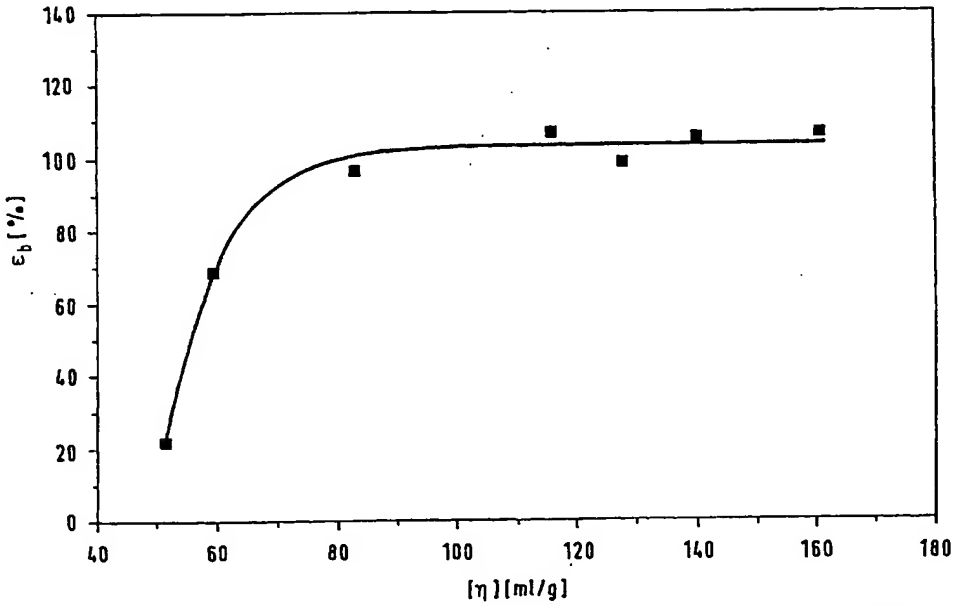

(57) Abstract: The invention relates to a method for producing a moulded body containing starch and to a homogenised material containing starch or a moulded body produced from the same. The inventive method is carried out in such a way that the value of the Staudinger index of the resulting material is at least 40 ml/g, which guarantees a strain at break of the extruded material of at least 100 % at encapsulation temperature. Soft capsules with a one-piece capsule cover in particular can be produced from this material in a rotary die process.

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(57) **Zusammenfassung:** Die Erfindung betrifft ein Verfahren zur Herstellung eines Stärke enthaltenden Formkörpers und eine homogenisierte Stärke enthaltende Masse bzw. einen daraus hergestellten Formkörper. Das Verfahren wird derart durchgeführt, dass der Wert des Staudinger-Index der damit hergestellten Masse mindestens 40 ml/g beträgt. Ein solcher Wert des Staudinger-Index gewährleistet eine Bruchdehnung des extrudierten Materials von wenigstens 100 % bei Verkapselungstemperatur, womit Weichkapseln mit einteiliger Kapselhülle im Rotary-Die-Prozess besonders bevorzugt hergestellt werden können.

METHOD FOR PRODUCING A MOULDED BODY COMPRISING STARCH

The invention relates to a method for producing a moulded body comprising starch, a homogenised material comprising starch and a device for producing a soft capsule in accordance with the preambles of the independent claims.

Moulded bodies consisting of biologically decomposable substances have for a long time been of extraordinary interest owing to the desire to protect the environment. As a consequence of the BSE problems, capsules with a capsule casing comprising gelatine-free materials have become particularly important for the purpose of administering pharmaceutically effective substances.

A series of publications describe the production of mating capsules made from starch, such as, for example, EP 118 240 and US 4,738,724. The mating capsules are pre-fabricated as a two-part casing using the injection moulding method and are filled with highly viscous or solid active ingredients possibly after an interim storage period. Owing to the fact that the mating connection is not leak-tight, mating capsules are not suitable for liquids which have a low viscosity. In addition, the method of producing a filled mating capsule is time-consuming and expensive as the procedural steps of producing and filling the capsule casing are performed separately from each other.

Capsules with a one-piece capsule casing which is made from gelatine and which can be produced in continuous, automated processes have been widely used for liquid capsule contents which can, in the widest sense, be pumped in. The capsule casing is produced and filled in a single procedural step. In these continuous, 1-step methods moulded parts are produced, from which the capsule casings are fitted together during and after the filling procedure by welding the outer edges of the moulded parts. The moulded parts are manufactured either by means of moulds which pull apart and fit together, such as is achieved, for example, in the Norton, Banner and Schering method or by means of rotating forming rollers, such as for example, in the rotary-die method and in the Accogel method ("Die Kapsel" [The Capsule] editors: Fahrig/Hofer, Stuttgart, 1983; Lachmann/Liebermann/Kanig, "The Theory and Practice of Industrial Pharmacy"; Third Edition, Philadelphia 1986). The capsules are filled using a metering pump which discharges a defined quantity of active ingredient during the stamping and welding of the moulded parts

in order to form a one-part capsule casing. The welding process, i.e. the formation of the seams, is generally performed using pressure and heat. The production costs are considerably reduced in comparison to the production of two-part mating capsules.

US 5,342,626 describes the production of capsules using the rotary-die method, wherein the capsule casing material is made from carrageenan, mannan-gums, such as for example, galacto- and glucomannans, gelan or mixtures thereof. These macro-molecular vegetable bio-polymers are, however, unacceptable for costs reasons as the raw materials are too expensive.

The production method for one-part capsules places a series of demands on the capsule casing material. One of the main criteria is the ability of the capsule casing material to form highly-elastic "endless" strips of sufficient strength. The capsule casing must rapidly dissolve as required in the gastro-intestinal tract in order to be able to release the active ingredients. The capsule casing material must be suitable for welding. The molecules of the material forming the moulded parts, in particular the macromolecules of the polymer, should ideally penetrate each other at the seam in order to ensure sufficient stability of the seam. Gelatine is almost ideal in fulfilling all these conditions and for a long time it could not be replaced as a material for one-piece capsule casings.

With respect to availability and cost criteria starch is also a desirable starting material for the production of one-piece capsule casings.

The production of starch films has already been described on numerous occasions, the combination of properties which a starch film of this type must comprise for the production of one-piece capsule casings has, however, not yet been disclosed.

EP 474 705 describes a method for producing starch moulded bodies by extrusion of a starch melt. The starch melt contains starch with an amylose content of more than 50% and additives. The water is removed from the melt before, during and/or after extrusion by application of negative pressure. The sheets extruded from this material have a stretch at break value of between 80 and 200%. Starches with a high amylose content are not suitable as capsule casing material since the retrogradation tendency of the amylose chains is detrimental to rapid dissolution of the capsule casing.

EP 0 397 819 discloses a method for producing thermoplastically workable starch, wherein the crystalline portion of the starch is below 5%. The method consists of mixing native starch with at least 10 wt.% of an additive which has a solubility parameter of at least 30.7$(MPa)^{1/2}$. The mixture is converted to a melt by the addition of heat in a temperature range between 120°C and 220°C. The water content of the starch is reduced in the melt to less than 5%. Before conversion to the thermoplastic state the molar mass of the starch used is greater than 1 000 000 Dalton, preferably between 3 000 000 Dalton and 10 000 000 Dalton. This method does produce a thermoplastic starch which is very suitable for processing into moulded bodies with sufficient strength but the stretch at break value of the moulded bodies produced with this thermoplastic starch only reaches values between 40 and 55%. The elasticity of the starch films is therefore too low for the production of one-piece capsule casings in continuous processes and means that the moulded bodies tear during manufacture or that cracks form in the finished capsule. The starch film also does not have the suitability for welding or the seam strength to meet the quality requirements placed on one-piece capsule casings.

EP 304 401 also describes a method for producing moulded objects from starch. The thermoplastic starch melt required for this purpose is produced from a pre-treated starch. However, the de-structuring (destruction of the crystalline regions) of the native starch and the subsequent homogenisation (conversion into the thermoplastic state) takes place at temperatures between 120°C and 190°C in a closed vessel with a water content between 10 and 20%. The stretch at break property of the starch films produced according to this method is not sufficient for the production of one-piece capsule casings. The starch films also have insufficient suitability for welding and seam strength.

EP 0 542 155 discloses biologically decomposable moulded substances which are suitable, amongst other things, for producing films. In addition to thermoplastically workable starch, the moulded substances contain cellulose derivatives. However, the stretch at break value does not exceed a value of 85%, which is not sufficient for the production of one-piece capsule casings in continuous processes. The suitability of the films for welding is unsatisfactory. Many of the polymer blends disclosed in EP 542 155 contains substances which are not permitted for pharmaceutical use and foodstuffs.

WO 97/35537 discloses one-piece capsules produced by means of rotating forming rollers

and containing gelled starch. The partial dissolution of the film surface has proved disadvantageous in the production of one-piece capsules with respect to transportation and pressure stability (when pushing the capsules out of the blister packs). The capsule casings are therefore too soft and too flexible in the region of the seam.

It is the object of the present invention to avoid the disadvantages of the prior art.

In particular it is the object of the present invention to provide gelatine-free moulded bodies and a method for producing the same. In particular, starch capsules with a one-piece capsule casing are to be produced.

It is a further object to provide a film which comprises starch and which can be processed to form one-piece capsule casings by means of semi-continuous or continuous processes, in particular by means of the rotary-die method.

It is a further object to provide a starch film for the production of the capsule casing, which has a stretch at break value of at least 100% during the encapsulation process and under the prevailing processing conditions.

It is a further object to provide starch films which are very suitable for welding.

It is a further object to provide starch capsules with a one-piece capsule casing which after a storage period of at least one year show no signs of leakage nor of changes to the dissolution rate of the capsule casing.

These objects are achieved by the features of the independent claims.

In particular they are achieved by a method of producing a moulded body comprising starch, in particular a soft capsule with a one-piece capsule casing, wherein the method includes the following steps:

a) conversion of a mixture containing at least one starch, water and at least one organic softener, with heating and kneading, into a thermoplastically workable, preferably homogenised substance, in a first processing device;

b) if appropriate, production of a storable intermediate product, in particular a granulated material after cooling of the substance obtained in step a) and subsequent conversion of the intermediate product into a thermoplastically workable substance in a second processing device;

c) production of at least one material strand, in particular an extruded film, at the output of the first or possible second processing device,

d) reforming the material strand into a moulded body in a continuous or intermittent moulding process;

e) if appropriate, drying the moulded body,

f) wherein steps a) to c) are carried out in such a way that in step d) the limiting viscosity number [η] of the starch in the substance forming the material strand has a value of not less than 40 ml/g, preferably at least 50 ml/g and more preferably at least 80 ml/g. Even better properties are obtained if the limiting viscosity number of the starch has a value of greater than or equal to 100 ml/g. The most advantageous properties are obtained with a limiting viscosity number value for the starch of greater than or equal to 130 ml/g. The limiting viscosity number must not exceed a maximum value of 1000 ml/g. In an advantageous embodiment the limiting viscosity number does not exceed 700 ml/g and more preferably does not exceed 300 ml/g.

The mixture used in step a) preferably contains starch in a weight range of 45 to 80 wt.% with respect to the total weight of the mixture.

The term "one-piece" should be understood to differentiate from two-part capsules which are produced by fitting together and/or sticking two capsule parts with superimposed outer edges. The one-piece capsule casing can be formed in a totally seamless manner - when formed from moulded parts - with a welded seam.

The term "soft capsule" is to be understood as a product of the current continuous and semi-continuous 1-step production methods for one-piece capsules reported in the literature. It serves less to define the softener content since hard capsules - as a term for two-piece capsules which are fitted together - can also have a softener content of up to 12% with respect to the total weight.

The terms "thermoplastically workable, melt and amorphous" are defined according to

Römpp Chemie Lexikon, editor: J. Falbe, M. Regitz, 9th edition, 1992, Georg Thieme Verlag, Stuttgart. The term starch should be understood as native starches and physically and/or chemically modified starches. For the mixture used in step a) of the method in accordance with the invention all starches are suitable regardless of the plants from which they are obtained. In a preferred embodiment starch is used having an amylopectin content of over 50% with respect to the total weight of the anhydrous starch. Physically and/or chemically modified potato starches have proved to be preferable for the method.

However, in the broadest sense all polyglucanes are suitable for the present invention, ie 1.4 and/or 1.6 poly-α-D-glucanes and/or mixtures between them.

In a preferred embodiment the starch is a hydroxypropylated starch. The degree of substitution (DS) is in the range of 0.01 to 0.5, preferably in the range of 0.05 to 0.25 and more preferably in the range of 0.1 to 0.15. In particular hydroxypropylated potato starches are used.

In a further preferred embodiment the starch is pre-gelatinized starch. Above a typical temperature for each type of starch and in aqueous starch suspensions after a maximum degree of swelling is reached, the starch grains begin to "dissolve", ie. there is an irreversible disintegration of the starch grains. The process is also termed "gelatinization". The gelatinization, ie the irreversible swelling of the starch grains at increased temperature up to 40 times the original volume is based on a gradual intake of water and dissolution of the hydrogen bridge bonds, which makes possible further hydration until the structure of the starch grain has completely disintegrated.

The conversion of the starch-containing mixture to the thermoplastic, preferably homogenised state in step a), and the subsequent processing steps b) and c) must take place under conditions which prevent uncontrolled breakdown of the amylose and amylopectin molecules to small fractions.

The interaction of all processing parameters such as temperature, pressure, dwell time and kneading power during steps a) to c) must be considered in order to prevent substantial breakdown of the starch molecules. In this way, for example, it is possible even at relatively high temperatures to avoid substantial breakdown of the starch molecules when the dwell

times of the starch-containing substance is [sic] kept short at these temperatures.

In a preferred embodiment the temperature of the substance does not exceed 160°C, preferably 140°C, more preferably 120°C and most advantageously 90°C, in the first and possible second processing device and during production of the material strand. In particular, at 160°C the pulping process in step a) should also be completed in less than 5 minutes, preferably less than 3 minutes.

In another preferred embodiment, the energy introduced into the substance by kneading in order to produce a thermoplastically workable homogenised substance in step a) to c) does not exceed 0.3 kWh/kg, preferably 0.2 kWh/gk and more preferably 0.175 kWh/kg.

The conversion into the thermoplastically workable state effects an irreversible swelling of the starch grains, which is a precondition to the substance being able to be converted into the homogenous state and being in the homogenised state even after cooling. By means of step a) to c) a substance is also produced, in which substantially no crystalline regions remain in the starch. Crystalline regions lead to the formation of specks in the material strand, ie. to a lack of homogeneity, which can be particularly disadvantageous when the material strand in step c) is an extruded film. The phrase "substantially no crystalline regions" should be understood to mean that these are destroyed to the extent that any impairment of the physical parameters of the extruded material relevant to the reforming cannot be attributed to the presence of crystalline regions.

The term "homogenous substance/material" or "homogenised substance/material" is to be understood to mean a material or a substance which has substantially the same physical properties (parameters) throughout the material. The absorption of atmospheric moisture can lead to slight deviations on the respective surfaces of the material or moulded parts. The substance is homogenous or homogenised when the number of starch grains still visible under the microscope when seen in cross section is less than one percent. For this purpose the substance is cooled in the thermoplastic state, cut into thin slices and analysed under the light microscope.

A homogenised substance/material is obtained when converting the mixture in the softened or even liquid state which results in a thermoplastically workable state. The majority of the

components forming the mixture (starch, organic softener, sliding and mould release agents) can be present in the molten state and with sufficiently long standing and/or mixing (kneading) time the substance will have substantially the same properties or chemical composition (homogenous substance) throughout the melt. This homogenous state is even retained during and after cooling of the thermoplastic state. No unmixing processes occur. This ensures uniform mechanical properties in the moulded body at ambient temperature.

The limiting viscosity number [η] or intrinsic viscosity is in the following relationship within a polymer homologous series with the molar mass, the weight average of the molecular weight distribution

$$[\eta] = K \times M^{\alpha;]}$$

wherein α] is an exponent depending upon the molecule structure and the K value is a constant dependent upon the dissolved substance and upon the solvent. Within the polymer homologous series the limiting viscosity number is higher the greater the molecular weight of the polymers when the other parameters remain unchanged. Measurement of the limiting viscosity number cannot give a determination of the absolute molecular weights.

The determination of absolute molecular masses in starches is known to be extremely difficult and the result is very strongly dependent upon the measuring method used. This is all the more true the more the molecules are branched. The results of the determination of the absolute molecular mass is [sic] therefore also given with a high level of uncertainty for amylopectin or amylopectin-containing starch. Since the determination of absolute molecular mass is also very expensive, the measurement of the limiting viscosity number provides values more rapidly, more reliably and more in accordance with the purpose.

Without providing exhaustive explanation, it is suspected that in the first place the polymerisation level of the amylopectin molecules in the starch used is responsible for the elasticity and therefore for the highest possible stretch at break value of the material strand produced in step d). A high stretch at break value is of great significance particularly for a strip-like film which is to be formed into a soft capsule in the rotary-die method.

It is possible to envisage that in addition to the inherent elasticity of the starch gels, which is provided in any case with a sufficient degree of polymerisation of the amylopectin molecules

which form them, a type of "starch network" can also be produced which is built up by entanglement and hooking together of the amylopectin molecules, and is supported by branching of the molecule. However, amylose molecules can also be included in this "starch network" if the degree of polymerisation is sufficiently high. The chemical substitution of the starch hydroxyl groups with ether, ester, vinyl and acetal formation can also be advantageous since they promote the formation of starch networks.

Step d) and step e) take place under conditions which avoid further breakdown of the amylose and amylopectin molecules. The moulded body obtained in step d) or e) therefore has substantially the same degree of polymerisation of the starch as effected by steps a) to c).

The presence of these networks and possibly also the presence of nano-crystals which may not be provable analytically and are also not visible as speck formation (analogous to soft PVC) is apparently responsible for the occurrence of a rubber plateau. The Young's modulus of elasticity E of amorphous non-cross-linked polymers and in particular linear polymers normally falls after passing through the region of the glass transition temperature with increasing temperature almost linearly up to 0°C. At sufficiently high temperature the polymers behave like a liquid. The characteristic of a rubber plateau, in contrast, is that the mechanical properties such as Young's modulus of elasticity E, the stretch at break ε_B, the maximum strength σ_m, etc. remain almost constant and almost independent of the temperature over a greater temperature range. A rubber plateau is normally only observed in cross-linked (chemical cross-linking) polymers (cf. Introduction to polymers, editor R. J. Young, P. A. Lovell, Chapman and Hall, London, 2nd edition 1991, pages 344/345). Surprisingly the substances of the present invention have a rubber plateau despite the absence of three-dimensional chemical cross-linking.

With this background it is possible also to understand the advantageous properties of a 1.4 and 1.6 polyglucane, which are co-crystallised with short linear chains of 1.4 polyglucanes. On the one hand, by means of the co-crystallisation further branches are produced which have a positive influence on the formation of a network and on the other hand non-visible nano-crystalline regions are produced. Amylopectins are preferably used as the 1.4 and 1.6 polyglucanes.

The substances in accordance with the invention, obtained by the production method in

accordance with the invention have - in the temperature range of about 20°C to about 80°C - mechanical properties such as ε_B, σ_m, E which are substantially independent of the temperature. The rubber plateau is of decisive significance for the reforming and filling of the films into filled moulded bodies. The Young's modulus of elasticity E of the starch-containing film in accordance with the invention at the time of reforming and filling in the rotary-die method is at most 2 MPa, preferably a maximum of 1 MPa. In other words the filling pressure of the filling material, which finally effects the formation of the capsule casing in the rotary-die method, under the supporting pressure of the filling wedge provided by the machine, should not be opposed by the film to such an extent that filling material escapes between the film and the filling wedge. It is, in fact, the temperature-independence of ε_B and σ_m between 40°C and 90°C which makes it possible to work the films produced from these substances into soft capsules using the rotary-die method.

The process of reforming the material strand into a moulded body, in particular the reforming of an extruded film into a one-piece soft capsule with the methods known in the prior art requires stretch at break values for the material strand, in particular for the film of at least 100% in the range of 40°C to 90°C preferably from 60°C to 80°C. In a preferred embodiment the stretch at break value of the material strand, in particular of the film, is at least 160% and more preferably at least 240%.

The strength σ_m of the material strand, in particular of the formed body produced therefrom must be at least 2 MPa at 25°C and 60% relative atmospheric moisture. In a preferred embodiment σ_m is greater than or equal to 3.5 MPa and more preferably greater than or equal to 5 MPa. This value ensures sufficient stability of the capsule casing at ambient temperature (packaging, storage, transportation safety and usage).

The filling takes place, however, with higher film temperatures which make a filling pressure of not more than 2 MPa necessary. This is achieved with a Young's modulus of elasticity E of less than or equal to 2 MPa at encapsulation temperature (40°C to 90°C) with the present substance. This has already been explained in the statements relating to the rubber plateau.

The total softener content of the mixture used in step a) amounts to at least 12 wt.% with respect to the weight of the anhydrous starch. In a preferred embodiment the softener content is in the range of 30 wt.% to 60 wt.% and more preferably in a range of 38 wt.% to 55 wt.%.

By conducting the method in accordance with the invention it is possible extensively to exclude strongly broken-down oligomers of the starch. This permits high overall quantities of softeners to be incorporated into the substance. The oligomers produced in the homogenisation methods of the previous prior art also produce a softening effect and the incorporation of large quantities of softeners would not be possible.

Softeners are preferably used which have a solubility parameter of equal to or > 16.3$(MPa)^{1/2}$. The organic softeners are selected from the group consisting of polyalcohols, organic acids, amines, acid amides and sulfoxides Polyalcohols are preferred. However, water also acts as a softener and therefore forms a part of the total softener content. The water content of the mixture used in step a) is in a range of 6 to 30 wt.% with respect to the total mixture.

The proportion of water of the mixture used in step a) can be changed as required in the method in accordance with the invention in step b) or c). The physical parameters, which are dependent on the water content, can therefore be subject to changes.

At least one additive in a weight range of 3.5 wt.% to 15 wt.%, preferably from 5 wt.% to 8 wt.% with respect to the total weight of the mixture can also be added to the mixture used in step a) depending on the required properties of the moulded body resulting from steps d) and e). The additives are selected from the group consisting of carbonates and hydrogen carbonates of the alkali and alkaline earth ions, further disintegration aids, fillers, colourants, antioxidants, physically and/or chemically modified biopolymers, particularly polysaccharides and vegetable polypeptides.

Opacity in the homogenised substance is, for example preferably achieved with the addition of titanium dioxide as a filler.

As a disintegration aid for the rapid decomposition of the capsule casing calcium carbonate and amylases are preferably added.

The group of physically and/or chemically modified biopolymers includes cellulose, in particular partially hydroxypropylated cellulose, alginates, carrageenan, galactomannans, glucomannans, casein.

In a preferred embodiment the mixture used in step a) additionally contains an internal sliding and mould release agent which is selected from the group consisting of lecithins, mono, di, or triglycerides of edible fatty acids, polyglycerine esters of edible fatty acids, polyethylene glycol esters of edible fatty acids, sugar esters of edible fatty acids and edible fatty acids.

The sliding and mould release agent is contained in the mixture preferably in a range of 0 to 4 wt.% with respect to the total weight of the mixture. It is preferably added to the mixture in a quantity of 0.5 to 2 wt.% and more preferably 0.8 to 1.5 wt.%. Advantageously the sliding and mould release agent is selected from the group consisting of glycerine monostearate and lecithin.

Edible fatty acids should be understood to mean the monocarboxylic acids occurring as acid components of the triglycerides of natural fats. The have an even number of C atoms and have an unbranched carbon skeleton. The chain length of the fatty acids varies from 2 to 26 C atoms. A large group of the fatty acids are saturated fatty acids.

The starch substance can be extruded in the thermoplastically workable state in step c) by means of a broad slit nozzle to form a starch film or starch strip. The substance can, however, also be left unformed from the thermoplastically workable state, cooled, dried and processed into a granulated material which is storable (with the exclusion of moisture). This granulated material is available for subsequent processing. Optionally it is also possible for only a portion of the necessary sliding or mould release agents, softeners and additives to be added to the substance to be processed into granulated material. For example, it is possible to dispense with the addition of the animal and/or vegetable fats in order to avoid undesirable colouring effects in the first processing device and to admix these fats only when the granulated material is remelted in the second processing device.

The extruded strips are now either further processed directly or possibly wound onto rolls for storage using synthetic material sheets as an intermediate layer.

Polyethylene proved to be a suitable sheet material.

The starch film obtained by means of the method in accordance with the invention can particularly be processed for the production of soft capsules in all installations known in the

art for the production of one-piece capsules. Continuous installations and particularly the rotary-die method have proved to the particularly suitable. The capsule wall is welded from two moulded part halves previously stamped from a starch film under a heating effect preferably greater than or equal to 50°C. Two "endless starch films" are guided by two adjacent oppositely rotating rolls or rollers with recesses therein. While the starch film is pressed into the recesses by the filling pressure of the filling substance and the capsule halves are thereby formed, the pumpable and injectable capsule filling is precisely metered by means of a valve and is introduced via a filling wedge into the entering angle of the forming rollers. The shape and size of the capsules is therefore dependent upon the geometric dimensions of the recesses in the rollers and the filling volume introduced.

Consequently the term capsule should therefore not only be understood as the typical capsule forms but also any other possible form of "casings" such as, for example spheres, cushion shapes and figures. Numerous further developments and deviations from this basic principle already exist.

The one-piece capsule casings produced using the starch film in accordance with the invention can be additionally coated, for example in order to delay the release of active substances.

The co-extrusion, coating and laminating of the starch film in accordance with the invention with materials with a film-forming property based on synthetic and/or natural polymers, additionally provides possibilities for creating certain properties in the capsule casing by means of a multi-layer sheet.

In particular, it is possible by multi-layer structuring to produce a starch sheet which has a coating on the inside which is very suitable for welding, while the outside is coated in such a way that a delaying effect is produced for the disintegration of the capsule.

Part of the present invention is also a homogenised, starch-containing substance which contains at least one substantially amorphous starch which is preferably present in a weight range of 45 to 80 wt.% with respect to the total weight of the substance, this substance also contains water, at least one organic softener in a proportion of at least 12 wt.% with respect to the weight of the anhydrous starch, wherein the limiting viscosity number of the starch in the

homogenised substance amounts to at least 40 ml/g.

A limiting viscosity number for the starch is preferably at least 50 ml/g, more preferably at least 80 ml/g. Particularly preferred is a limiting viscosity number for the starch of greater than or equal to 100 ml/g. Even better properties are obtained with a limiting viscosity number for the starch of greater than or equal to 130 ml/g. The limiting viscosity number of the starch should not exceed 1000 ml/g, preferably 700 ml/g and more preferably 300 ml/g.

Advantageously a starch is used with an amylopectin content of greater than or equal to 50 wt.% with respect to the weight of the anhydrous starch.

The organic softener content is advantageously in the range of 30 wt.% to 60 wt.%, preferably in a range of 38 wt.% to 55 wt.% and still more preferably in a range of 40 to 50 wt.% with respect to the total weight of the substance.

With respect to the embodiments of the softeners, starch and additives, reference is made to the corresponding statements relating to the method.

In a preferred embodiment, the moulded body has a water content of at most 15 wt.% with respect to the total weight of the substance.

When the substance is formed as a film and is to be used for the production of one-piece capsule casings in the rotary-die method, a stretch at break value at the encapsulation temperature of 40° to 90°C of at least 100% is required, however, the stretch at break value is preferably at least 160% and more preferably at least 240%.

The moulded body, in particular the soft capsule casing formed from the film has a strength σ_m of preferably at least 3.5 MPa and more preferably at least 5 MPa at 25°C and 60% relative atmospheric moisture.

Moulded bodies produced from the substance in accordance with the invention are also part of the invention.

Furthermore, part of the invention is a one-piece capsule casing which contains starch with a

limiting viscosity number of at least 40 ml/g, preferably at least 50 ml/g and more preferably at least 80 ml/g. Particularly preferred is a capsule with a limiting viscosity number for the starch of 100 ml/g and more preferably a limiting viscosity number of 130 ml/g.

The substances in accordance with the invention are very suitable for the production of multi-chamber or two-chamber capsules as described for instance in WO 00/28976. Since the water content of the film or films can be set low, almost no stresses occur in the finished dried capsules, in particular in the separating walls forming the chambers, which substantially increases the stability of the multi-chamber capsule in comparison to multi-chamber soft gelatine capsules.

For example, two-chamber capsules can be produced with one chamber filled with powder or granulated material and with the other chamber containing a liquid.

The moulded body, in particular the capsule casing has a thickness in the range between 0.1 and 2 mm, preferably between 0.2 and 0.6 mm.

In a further preferred embodiment, the moulded body, in particular the soft capsule casing consists of a multi-layer film. At least two of the films have a different chemical composition.

Apart from the production of single-layer capsule casings, the thermoplastically workable starch melt can also be used to produce any other type of moulded body, in particular packaging materials. In the thermoplastic state the substance is workable, in particular, extrudable.

An exemplified embodiment of the invention with respect to the device is illustrated in the figures and described in more detail hereinunder. In the drawings:

Figure 1 illustrates the strain at break [ε_b] of a starch-containing substance in dependence upon the limiting viscosity number [η],

Figure 2 shows a highly schematic illustration of a filling and forming station for the rotary-die method, and

Figure 3 shows a symbolic illustration of a double screw extruder with the temperature ratios prevailing therein,

Figure 4 shows the Young's modulus of elasticity E [MPa] of a starch-containing, homogenised substance in accordance with the invention in dependence upon the temperature (conditioned 50% relative atmospheric moisture).

The measurement of the stretch at break and of the Young's modulus of elasticity E is carried out according to DIN standard 53455 or DIN EN ISO 527-1 to ISO 527-3. The measurement of stretch at break is carried out according to this DIN standard at the corresponding encapsulation temperature.

The measurement of the limiting viscosity number [η] takes place in accordance with the DIN standard: DIN 51562-1 to 51562-4. However, the softener content of the samples and its influence on the holding times in the Ubbelohde viscometer had to be taken into account. For this purpose the influence of the softener content on the passage time t_0 was first determined, by means of the calibration lines obtained the passage times $t_{0Weichg}$ could then be calculated for any softener content according to

$$t_{0Weichg} = t_0 \bullet (1.00002 + 0.00238 \bullet C_{Weichg})$$

wherein C_{Weichg} is the present concentration of softener in mg/ml. The limiting viscosity numbers determined for the disintegrated starches are given in Table 1 together with the mechanical properties of the associated samples.

The production of the samples which in Figure 1 demonstrate the connection between the stretch at break value and the limiting viscosity number is as follows:

starch	56.2 to 56.9 wt.%
glycerine:	41.8 wt.% with respect to the anhydrous starch content
water:	1.3 - 2.0 wt.% with respect to the total weight of the mixture.

The mixtures were homogenised in a Brabender mixer at 160rpm and a kneading time of 15 minutes at each of the varied kneading temperatures of 110°C, 160°C, 200°C, 220°C and 235°C.

Figure 1 shows the dependency of the stretch at break value of the starch-containing substance upon the limiting viscosity number of the starch. Figure 1 and the associated Table 1 show that with increasing temperature in the Brabender mixer the limiting viscosity number of the starch decreases, ie. in a composition which is otherwise unchanged and with unchanged process parameters (the only variable is the temperature) the disintegration rate of the starch increases. A stretch at break value of 97% is achieved with a limiting viscosity number of 82.8 ml/g. Thereafter the stretch at break value moves asymptotically towards a limit value of about 105% as the value of the limiting viscosity number increases.

The starting value of the limiting viscosity number, ie. the value from which a clear increase in the stretch at break value is observed is independent of the proportion of softener and only dependent upon the molecular weight average of the starch molecules or the corresponding limiting viscosity number. With a lower proportion for the softener portion the curve is generally flatter ie. moved towards lower stretch at break values.

Similarly when the limiting viscosity number of the substance as a whole is measured, the value of the index is substantially only dependent upon the degree of polymerisation of the starch. The value of the limiting viscosity number is substantially independent of the remaining components of the substance (or their small influence can be taken into account arithmetically).

The maximum strength σ_m was determined in accordance with DIN standard 53455 or DIN EN ISO 527-1 to ISO 527-3. σ_m also shows a dependency upon the limiting viscosity number, ie the degree of disintegration of the starch. The lower the limiting viscosity number when other conditions are unchanged, the lower the σ_m.

The filling and forming station generally designated by 1 in Figure 2 has a forming roller pair 6, 6', which is generally known per se, for the encapsulation, wherein the recesses required for the shaping of the capsules are disposed in the surfaces of the forming rollers. In the entering angle of the forming roller pair a filling wedge 5 is disposed by which, using a delivery pump 4, the filling can be introduced. In the present exemplified embodiment the capsule casing consists of two layers with different material properties which are formed by the two starch films 7a, 7a' on the one hand and 7b, 7b' on the other. These two starch films are prepared in the screw extruders 2a, 2a' and 2b, 2b' and are supplied via diverting rollers 3 directly and at

the same delivery rate to the entering angle of the forming roller pair 6, 6'. The screw extruders are disposed immediately next to the filling and forming station and may be disposed on the same machine frame.

The starch films are formed and welded into a one-piece soft capsule between the forming roller pair, wherein they enclose the filler. The individual capsules 9 are caught and, if necessary, passed to a drying process while the remaining film skeleton 8 may possibly be reworked into new capsules by recycling.

The placement of the extruder immediately adjacent to the forming and filling station and the "in-line" conveyance of the extruded film into the forming and filling station (without intermediate storage) is naturally possible at any time, ie. even when producing single-layer capsule casings (current rotary-die method).

Figure 3 shows in a greatly simplified manner a double screw extruder 10 which in this case is composed of twelve individual housing blocks 1 - 12. The housing blocks are numbered consecutively from left to right. Each housing block can be heated electrically by a separate control circuit and/or can be cooled with cold water via valve-controlled inlets. Furthermore, individual blocks can be provided with connection fittings as explained in more detail hereinunder. The present case relates to a narrow-combing double screw extruder with the same rotational direction, wherein the diameter of a screw is 44 mm. The length of the whole screw shaft is 2'112 mm [sic] which corresponds to a length to diameter ratio of 48. At the end of the extruder the material is dispensed via a nozzle 14. This nozzle can have, for example twelve bores of 2 mm in diameter. It would be feasible to chop the individual material strands while hot in order to form a granulated material and then to supply them to a fluid bed dryer. However, it would also be possible to draw a completed material film directly from the nozzle 14.

At suitable points on the screws 2 kneading discs 13 of different configurations are disposed in order to achieve the most homogenous possible kneading of the material mixture. The block 1 is water-cooled and provided with a powder intake 15. The block 2 is closed, while on the block 3 an injection nozzle 16 for metering liquid into the kneading chamber is disposed. At the transition region of the blocks 2 and 3 fine neutral kneading discs 13 are disposed. The blocks 4 to 6 are also closed, wherein on block 5 wide, neutral and reversing

kneading discs are provided. Block 7 has a connection line 17 which is connected to a source of negative pressure. On block 8 another powder intake 18 is disposed and the screw is provided with fine, neutral or conveyor kneading discs. Block 9 also has an injection nozzle 19, while block 10 is closed. On the other hand, the screw in block 10 has wide, neutral and reversing kneading discs. Block 11 has a further extraction line 20 which can be connected to a source of negative pressure or to atmosphere. Block 12 is closed, the screw therein, however, has middle conveyor kneading discs.

Below the schematic conveyor screw a temperature curve is drawn. The adjustable temperature precision is +/-3°C. The given temperatures are the block temperatures which do not necessarily have to be identical to the temperature in the melt. The temperature in the melt is evidently also influenced by other parameters, in particular by the rotational speed of the screw. During extrusion it is therefore necessary to take account of these conditions and to match the adjustable variables to each other in such a way that optimal material properties are obtained.

In the exemplified embodiment described with the aid of this figure, a rotational speed of 340 rotations per minute (rpm) is used. The whole throughput amounts to about 34.3kg/h and the energy consumption is about 0.175 kWh/kg. At block 1 which is kept to 20°C, 20 kg/h (about 60%) of starch powder is metered in. The powder is drawn in by thrust edges and supplied to the blocks 2 and 3 which are heated to 100°C. In block 3 11kg/h (about 30%) of glycerine is metered in at a working pressure of at least 10 bar via a gravimetric piston pump. In the closed blocks 4 to 6 the temperature is increased to 140°C. In block 7 a negative pressure of 800 mbar is applied, wherein about 6% of the water leaves. The temperature is then returned to 110°C. At block 8 is added 1.4kg/h (about 10%) calcium carbonate. If necessary, 1.9kg/h (about 5 to 8%) of glycerine can be metered in at block 9. The working pressure also amounts to at least 10 bar. If this connection is not required, it is closed by a blind stopper. Negative pressure is again applied at block 11, wherein about 2 to 4% of the water leaves. However, merely atmospheric ventilation may also be sufficient.

The temperature of the melt must not exceed 160°C at any point in the extruder because if it does, a thermal breakdown of the starch is initiated. It is also the case that there is less of a thermal change in the starch the shorter the melt's exposure to a high temperature. An optimal relationship must be achieved between the temperature control and material

throughput.

In Figure 4 the temperature dependency of the Young's modulus of elasticity E is illustrated. The composition of the test pieces corresponds to Example 2 (continuous line). In comparison to this, the theoretical temperature behaviour of a thermoplastic material of similar glass transition temperature is shown. While the E modulus of the "normal" thermoplastic (broken line) rapidly falls to zero in a linear manner, in the test pieces the E modulus in a range of 40°C to about 70°C is virtually independent of the temperature. This behaviour is, amongst other things, also responsible for the advantageous properties of the present invention.

The present invention will be explained further with the aid of the following examples:

Example 1

The following components are continuously metered via a two-shaft extruder (type ZSK 30, Werner & Pfleiderer) and converted into the thermoplastically workable state.

Starch:	7.7kg/h
Lecithin:	0.147kg/h
Glycerine monostearate:	0.147kg/h
Glycerine (99.5 purity)	4.47kg/h
Calcium carbonate, precipitated	1.0kg/h

Wherein extrusion is carried out with a screw rotational speed of 180rpm under the following conditions (see Figure 2):

Block 1:	25°C
Block 2 and 3:	100°C
Block 4 to 6:	140°C
Block 7 to 9:	110°C
Block 10 to 12:	110°C
Nozzle	110°C

With respect to the anhydrous starch this corresponds to a glycerine content of 38.77%. With

respect to the anhydrous end product the following proportions are achieved:

Lecithin:	1.11%
Glycerine monostearate	1.11%
Starch (anhydrous)	55.15%
CaCO3:	7.76%
Glycerine:	34.87%

The specific energy consumption during the extrusion: 0.275 kWh/kg

The extruded film is suitable for the production of moulded bodies of any type and is particularly advantageous for the production of one-piece capsule casings by the rotary-die method.

The starch in the substance obtained according to this example has a limiting viscosity number of 107.2 ml/g ± 5% and the extruded film has a stretch at break value at the encapsulation temperature of 102% ± 10%.

Example 2

The following components are continuously metered via a two-shaft extruder (type ZSK 30, Werner & Pfleiderer) and converted into the thermoplastically workable state.

Starch:	7.7kg/h
Lecithin:	0.147kg/h
Glycerine monostearate:	0.147kg/h
Glycerine (99.5% purity)	4.67kg/h

Wherein extrusion is carried out with a screw rotational speed of 260rpm under the same conditions as in Example 1.

In block 4 a vacuum (eg 800 mbar) can alternatively be applied in order to draw of excess water (from the starch powder).

With respect to the anhydrous starch this corresponds to a glycerine content of 39.81%. With

respect to the anhydrous end product the following proportions are achieved:

Lecithin:	1.18%
Glycerine monostearate	1.18%
Starch (anhydrous)	58.81%

The extruded film is suitable for the production of moulded bodies of any type and is particularly advantageous for the production of one-piece capsule casings by the rotary-die method.

The starch in the substance obtained according to this example has a limiting viscosity number of 115.6 ml/g ± 5% and the extruded film has a stretch at break value at the encapsulation temperature of 107% ± 10%.

Example 3

The following components are continuously metered via a two-shaft extruder (type ZSK 235, Krupp, Werner & Pfleiderer) and converted into the thermoplastically workable state.

All details in wt.%:

Starch:	57.88%
Lecithin:	1.06%
Glycerine monostearate:	1.06%
Glycerine (98% purity):	3.64%
Sorbitol syrup (30% water content)	36.36%

wherein the following settings were given:
Screw rotational speed of the two-shaft extruder = 150 rpm.
In blocks 7 and 10 a pressure of 400 mbar was applied by a vacuum pump in order to draw of excess water (which entered the process predominantly via the moisture content of the starch and of the sorbitol syrup).

Block temperatures:

Block 1:	20°C
Block 2 & 3:	110°C

Block 4 & 5:	140°C
Block 6 & 7:	120°C
Block 8 & 9:	110°C
Block 10 - 12:	100°C
Nozzle	95°C

The specific energy consumption during the extrusion was 0.195 kWh/kg.
With respect to the anhydrous end product the following composition is achieved (all details in percentage by weight):

Starch (anhydrous):	61.25%
Lecithin:	1.31%
Glycerine monostearate:	1.32%
Glycerine:	4.44%
Sorbitol:	31.69%

The extruded film is suitable for the production of moulded bodies of any type and is particularly advantageous for the production of one-piece capsule casings by the rotary-die method.

The starch in the substance obtained according to this example has a limiting viscosity number of 92.5 ml/g ± 5% and the extruded film has a stretch at break value at the encapsulation temperature of 188% ± 10%.

Example 4:

Extrusion conditions as in Example 3 and with the following metering:

The following components are continuously metered via a two-shaft extruder (type ZSK 25, Krupp, Werner & Pfleiderer) and converted into the thermoplastically workable state:
All details in wt.%:

Starch:	58.92%
Glycerine monostearate:	1.08%
Glycerine (98% purity):	3.64%
Sorbitol syrup (30% water content)	36.36%

The specific energy consumption during the extrusion was 0.265 kWh/kg.

With respect to the anhydrous end product the following composition is achieved (all details in percentage by weight):

Starch (anhydrous):	62.46%
Glycerine monostearate:	1.35%
Glycerine:	4.44%
Sorbitol:	31.75%

The extruded film is suitable for the production of moulded bodies of any type and is particularly advantageous for the production of one-piece capsule casings by the rotary-die method.

The starch in the substance obtained according to this example has a limiting viscosity number of 128.3 ml/g ± 5% and the extruded film has a stretch at break value at the encapsulation temperature of 156% ± 10%.

Example 5:

Extrusion conditions as in Example 3 and with the following metering:

The following components are continuously metered via a two-shaft extruder (type ZSK 25, Krupp, Werner & Pfleiderer) and converted into the thermoplastically workable state:
All details in wt.%:

Starch:	62.95%
Glycerine monostearate:	1.15%
Glycerine (98% purity):	8.28%
Sorbitol (30% water content)	27.61%

The specific energy consumption during the extrusion was 0.295 kWh/kg.

With respect to the anhydrous end product the following composition is achieved (all details in percentage by weight):

Starch (anhydrous):	65.17%
Glycerine monostearate:	1.40%
Glycerine:	9.89%
Sorbitol:	23.54%

The extruded film is suitable for the production of moulded bodies of any type and is particularly advantageous for the production of one-piece capsule casings by the rotary-die method.

The starch in the substance obtained according to this example has a limiting viscosity number of 79.3 ml/g ± 5% and the extruded film has a stretch at break value at the encapsulation temperature of 203% ± 10%.

Example 6:

Extrusion conditions as in Example 3 and with the following metering:

The following components are continuously metered via a two-shaft extruder (type ZSK 25, Krupp, Werner & Pfleiderer) and converted into the thermoplastically workable state:

All details in wt.%:

Starch:	55.80%
Glycerine monostearate:	1.02%
Glycerine (98% purity):	3.93%
Sorbitol syrup (30% water content)	19.63%
Maltitol syrup (25% water content)	19.63%

The specific energy consumption during the extrusion was 0.225 kWh/kg.

With respect to the anhydrous end product the following composition is achieved (all details in percentage by weight):

Starch (anhydrous):	58.73%
Glycerine monostearate:	1.26%
Glycerine:	4.76%
Sorbitol:	17.01%

Maltitol: 18.23%

The extruded film is suitable for the production of moulded bodies of any type and is particularly advantageous for the production of one-piece capsule casings by the rotary-die method.

The starch in the substance obtained according to this example has a limiting viscosity number of 74.8 ml/g ± 5% and the extruded film has a stretch at break value at the encapsulation temperature of 184% ± 10%.

Example 7:

Extrusion conditions as in Example 3 and with the following metering:

The following components are continuously metered via a two-shaft extruder (type ZSK 25, Krupp, Werner & Pfleiderer) and converted into the thermoplastically workable state:
All details in wt.%:

Starch:	59.88%
Glycerine monostearate:	1.10%
Glycerine (98% purity):	3.55%
Sorbitol syrup (with a high proportion of hydrogenated oligosaccharides)	17.74%
Sorbitol (30% water content)	17.74%

The specific energy consumption during the extrusion was 0.185 kWh/kg.

With respect to the anhydrous end product the following composition is achieved (all details in percentage by weight):

Starch (anhydrous):	63.38%
Glycerine monostearate:	1.37%
Glycerine:	4.33%
Sorbitol:	15.46%
Sorbitol with a high proportion of hydrogenated oligosaccharides	15.46%

The extruded film is suitable for the production of moulded bodies of any type and is particularly advantageous for the production of one-piece capsule casings by the rotary-die method.

The starch in the substance obtained according to this example has a limiting viscosity number of 88.1 ml/g ±5% and the extruded film has a stretch at break value at the encapsulation temperature of 240% ± 10%.

Table 1: The mechanical properties of the starch films with 41.8% glycerine in dependence upon the limiting viscosity number [η]

T_B °C	H_2O %	[η] ml/g	d mm	σ_m MPa	ε_b %
110	1.77	160.5	0.72	7.0 +/- 0.3	107 +/- 6
140	1.80	139.9	0.65	6.8 +/- 0.4	106 +/- 18
160	1.55	127.9	0.64	6.3 +/- 0.4	99 +/- 5
180	1.54	115.6	0.64	6.9 +/- 0.2	107 +/- 9
220	1.66	82.8	0.73	4.8 +/- 0.4	97 +/- 23
200	1.55	59.2	0.61	4.9 +/- 0.5	69 +/- 23
235	1.30	51.5	0.87	9.0 +/- 0.7	22 +/- 24

Claims

1 Method for producing a moulded body comprising starch, in particular a soft capsule with a one-piece capsule casing, characterised by the following steps

a) conversion of a mixture containing at least one starch preferably in a weight range of 45 to 80 wt.% with respect to the total weight of the mixture, water and at least one organic softener, with heating and kneading, into a thermoplastically workable, preferably homogenised substance, in a first processing device;

b) if appropriate, production of a storable intermediate product, in particular a granulated material, after cooling of the substance obtained in step a) and subsequent heating of the intermediate product into a thermoplastically workable substance in a second processing device;

c) production of at least one material strand, in particular an extruded film, at the output of the first or possible second processing device,

d) reforming the material strand into a moulded body in a continuous or intermittent moulding process;

e) if appropriate, drying the moulded body,

characterised in that the steps a) to c) are carried out in such a way that in step d) the limiting viscosity number of the starch in the substance forming the material strand has a value of not less than 40 ml/g, preferably at least 50 ml/g and more preferably at least 80 ml/g.

2 Method according to claim 1, characterised in that the mixture used in step a) additionally contains an internal sliding or mould release agent which is selected from the group consisting of lecithins, mono, di, or triglycerides of edible fatty acids, in particular glycerine monostearate, polyglycerine esters of edible fatty acids, polyethylene esters of edible fatty acids, sugar esters of edible fatty acids and edible fatty acids, pyrrolidones.

3 Method according to any one of claims 1 or 2, characterised in that the organic softener content is at least 12 wt.% with respect to the weight of the anhydrous starch, preferably in a range of 30 wt.% to 60 wt.% and more preferably in a range of 38 wt.% to 55 wt.%.

4 Method according to any one of claims 1 to 3, characterised in that the temperature of the substance in steps a) to c) does not exceed 160°C, preferably 120°C and more preferably

90°C.

5 Method according to any one of claims 1 to 4, characterised in that the energy introduced into the substance by kneading in steps a) to c) does not exceed 0.3 kWh/kg, preferably 0.2 kWh/gk and more preferably 0.175 kWh/kg.

6 Method according to any one of claims 1 to 5, characterised in that at least the melting in the first processing device takes place in a double screw extruder with the same rotational direction and that individual portions of the extruder with respect to the longitudinal direction of the screws are heated to different temperatures.

7 Method according to any one of claims 1 to 6, characterised in that in step c) the material strand is extruded as a flat film which is stored, preferably in the form of rolls, with intermediate layers of non-stick material, and is formed at a later time into moulded parts, particularly capsule casings.

8 Method according to one of claims 1 to 7, charactered in that the reforming in step d) includes two homogenous material films which in a conventional encapsulation process, in particular by the rotary-die method, are formed into soft capsules with a one-piece capsule casing, wherein the fitting together of the capsule casing parts and the filling of the capsule casing take place in one working step.

9 Method according to one of claims 1 to 8, characterised in that in step c) a film is extruded as a tube, the tube is first slit and further processed as a flat strip in step d).

10 Moulded body, in particular a one-piece soft capsule casing, produced according to the method in accordance with any one of claims 1 to 9.

11 Homogenised, starch-containing substance, containing preferably at least 45 wt.% of an amorphous starch with an amylopectin content of preferably greater than or equal to 50 wt.% with respect to the weight of the anhydrous starch, water, at least one organic softener in a proportion of at least 12 wt.% with respect to the weight of the anhydrous starch, characterised in that the value of the limiting viscosity number [η] of the starch in the homogenised substance is at least 40 ml/g, preferably at least 50 ml/g and more

preferably at least 80 ml/g.

12 Substance according to claim 11, characterised in that the substance additionally contains at least one sliding and mould-release agent selected from the group consisting of lecithins, mono, di, and triglycerides of edible fatty acids, in particular glycerine monostearate, polyglycerine esters of edible fatty acids, polyethylene esters of edible fatty acids, sugar esters of edible fatty acids and edible fatty acids.

13 Substance according to any one of claims 11 or 12, characterised in that the softener is selected from the group consisting of polyalcohols, in particular glycerine, organic acids, hydroxy acids, amines, acid amides, sulfoxides and pyrrolidones.

14 Substance according to any one of claims 11 to 13, characterised in that the substance additionally contains at least one additive in a weight range of 3.5 wt.% to 15 wt.% with respect to the total weight of the substance, preferably from 5 wt.% to 8 wt.%, wherein the additive is selected from the group consisting of carbonates and/or hydrogen carbonates of the alkali and/or alkaline earth ions, preferably calcium carbonate, amylases, further disintegration aids, colourants, preservatives, antioxidants, physically and/or chemically modified biopolymers and vegetable polypeptides.

15 Substance according to any one of claims 11 to 14, characterised in that the organic softener content is at least 12 wt.% with respect to the weight of the anhydrous starch, preferably in a range of 30 wt.% to 60 wt.% and more preferably in a range of 38 wt.% to 55 wt.%.

16 Moulded body, in particular one-piece soft capsule casing, consisting of a substance according to any one of claims 11 to 15.

17 Moulded body, in particular soft capsule casing, according to claim 16, characterised in that at temperatures between 40°C and 90°C the moulded body has a stretch at break value of at least 100%, preferably at least 160% and more preferably at least 240%.

18 Moulded body according to any one of claims 16 or 17, characterised in that at 25°C and with 60% relative atmospheric moisture the moulded body has a strength σ_m of at least

3.5 MPa, preferably 5 MPa.

19 Moulded body according to any one of claims 16 to 18, characterised in that the moulded body is a soft capsule and that the capsule casing has a thickness in the range between 0.1 and 2 mm, preferably between 0.2 and 0.6 mm.

20 Moulded body according to any one of claims 16 to 19, characterised in that the moulded body contains a multi-layer film and that at least two of the films have a different chemical composition.

21 Moulded body according to any one of claims 16 to 20, characterised in that the moulded body is a multi-chamber capsule with a one-piece capsule casing, wherein the multi-chamber capsule has at least one separating wall in order are created [sic] at least two closed compartments in the capsule.